Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/IL05/000871

International filing date: 11 August 2005 (11.08.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/600,725
Filing date: 12 August 2004 (12.08.2004)

Date of receipt at the International Bureau: 01 December 2005 (01.12.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

PCT/IL2005/000871
10 NOV 2005

PA 1371081

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

September 23, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: *60/600,725*
FILING DATE: *August 12, 2004*

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

T. Lawrence

T. LAWRENCE
Certifying Officer

UNITED STATES PATENT AND TRADEMARK OFFICE
DEPARTMENT OF COMMERCE

15992 U.S. PTO

PTO/SB/16 (04-04)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

22151 U.S.PTO
60/600725

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
SHLOMI	BEN-ARI	BINYAMINA - ISRAEL

Additional inventors are being named on the ____________ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

MEDICAL NEVIGATION SYSTEM BASE ON DIFFERENTIAL SENSOR

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☐ Customer Number:

OR

☐ Firm or Individual Name	Dr. SHLOMI BEN-ARI				
Address	P.O.B - 368				
Address	HASHOSHANA St. 23				
City	BINYAMINA	State		Zip	
Country	ISRAEL	Telephone		Fax	

ENCLOSED APPLICATION PARTS ***(check all that apply)***

☒ Specification *Number of Pages* 10
☐ Drawing(s) *Number of Sheets* ____
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number ____
☐ Other (specify) ____

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees.
☐ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: ____
☒ Payment by credit card. Form PTO-2038 is attached.

FILING FEE Amount ($): 160 $

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are: ____

Respectfully submitted,

SIGNATURE ____

TYPED or PRINTED NAME SHLOMI BEN-ARI

TELEPHONE ____

Date 22/7/04

REGISTRATION NO. ____
(if appropriate)
Docket Number: ____

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Medical Navigation System Based on differential sensor

Provisional Patent

Written by:
Shlomi Ben-ari

Table of Contents

Table of Figures

1. Scope

This paper provides a description of a novel intravascular navigation system based on differential radiation sensing. It is written in order to be submitted as a provisional patent.

2. Background

Existing medical imaging systems (e.g. MRI, MRA, CT, Nuclear imaging) provide a means for detection of malformation in body tissues. In most cases, reaching the lesion for biopsy or treatment requires a surgical procedure that causes damage to healthy tissue.
An intravascular approach can often be utilized for reaching the suspected lesion using a catheter. A navigation system that locates the catheter tip is required in order to guide the operator to the exact location of the lesion during the procedure.

2.1. The medical need

The identified need is a system that tracks the location of a medical tool (such as a catheter tip, needle, laparoscopic tool etc) relative to some external reference frame.
This system is referred as a Tracking system or Navigation system.

2.1.1. Required tracking system characteristics

- Provide 3 dimensional tracking of a small element
    - Sensor size 0.1 to 1 mm diameter, Goal: below 0.1 mm
- Accurate tracking - less than 1 mm error, in the harsh environment of standard operating arena
    - In presence of metal elements and tools
    - EM Radiation emitted by medical equipment
- Does not require clear line of sight to the tracked element
- Does not require rigid connection between the tracked element and the outside world
    - To allow intravascular procedures
- Does not expose the patient or the operator to harmful doses of radiation
- Wireless tracked element is preferred

2.2. Prior art medical tracking solutions

2.2.1. Electro Magnetic Tracker

Most of the existing intravascular navigation systems are based on the so called EM Tracker (Electro Magnetic). The EM tracker is based on generating a quasi static magnetic field within the volume of interest. The tracked element senses the field in its vicinity and its location is calculated based on its measurement of the local field.
EM tracker disadvantages:

- The EM tracker is found to be vulnerable to EMI (Electro Magnetic Interference) due to emission from PC monitors and other medical equipment.
- The EM tracker accuracy is degraded due to metallic elements in the vicinity of the tracker.
- Tracking a tip of a catheter requires routing wires along the catheter.

2.2.2. Optical Tracker

Optical tracking is based on analyzing images of a number of cameras viewing the tracked element (Light source or Reflector).

Optical Tracker disadvantages:

- Applicable only to situations where the tracked element is rigidly attached to a visible light source or reflector. Thus not applicable to intravascular navigation
- Requires a clear path from the cameras to the tracked element.

3. The proposed solution for intravascular tracking system

The proposed tracking solution is based on utilizing a radiation form to which the human body is relatively transparent (e.g. gamma rays, low frequency RF, etc). The tracked element either emits or reflects the radiation of interest, and its location within the body is measured by sampling the radiation from outside the body.
The tracked element can be a small amount of radioactive material, a miniature RF transmitter or an RF reflector.

3.1. Concept overview

The proposed tracker concept is to utilize a set of tracking modules. Each tracking module provides one angle defining a plane within which the tracked element lies. By combining the information from several modules at different locations, the system can accurately calculate the location of the tracked element in three dimensions.
The following section provides a bottom up description of the tracking system, starting with the basic tracking modules and from there to the system level concepts.

3.1.1. Basic Tracking Module (BTM)

3.1.1.1. BTM Structure

Following is a conceptual view of the Basic tracking module.

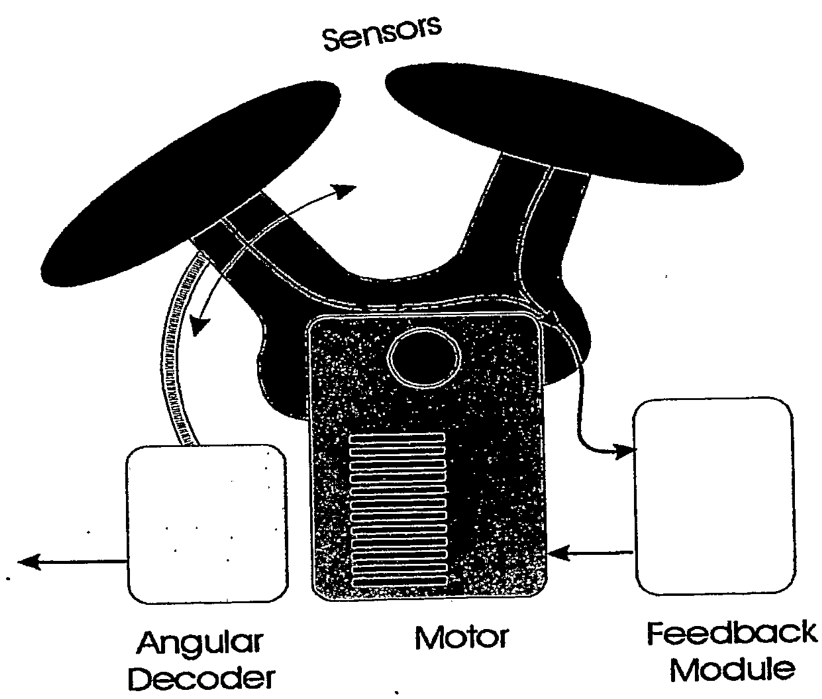

Figure 1 : Basic Tracking Module – conceptual view

The Basic Tracking Module (referred as BTM) is composed of the following:

- 2 radiation detectors.
  Geometrically arranged such that the ratio between their readings is proportional to the relative location of the radiation source (in at least one axis)
- Moving mechanical mount that can rotate (or translate) the above sensors.
- Feedback mechanism.
  The function of this module is to rotate (or translate) the sensors until their readings are identical. Digital or Analog Signal processing may be utilized for this purpose.
- Orientation (or position) decoder.
  The function of this device is to measure the actual orientation (or position) of the sensors in which the readings are identical.

3.1.1.2. BTM Functionality

The BTM output is the angle (about the axis of the BTM) from the BTM to the radiator.

3.1.2. Tracker System

The tracker system's objective is to calculate the position of the tracked element (radiator).

Following is a schematic illustration of such a system:

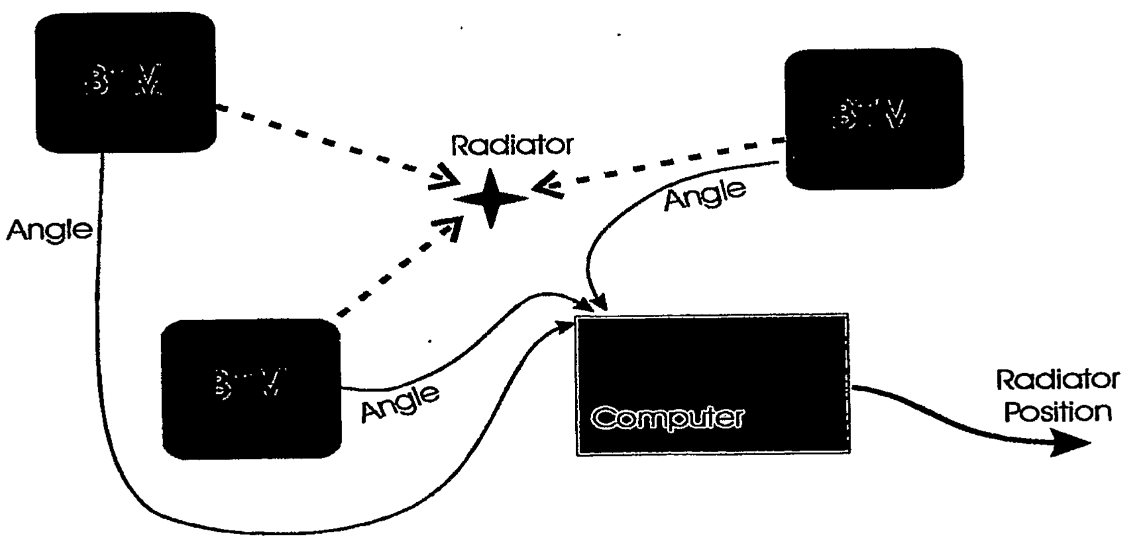

Figure 2 : Tracker system structure

The tracking system is composed of several Basic Tracking Modules (BTMs), each providing the angle from it to the radiator about one axis.

Knowing the position and axis orientation of all of the BTMs in the system, one can calculate the radiator's position in space relative to the BTMs.
Each BTM output defines a plane in which the radiator resides; this plane is defined by the measured angle. It is known that the intersection of three planes defines a singular point in space. Thus, a system comprising of three BTMs is able to locate the radiator.
If more than three BTMs are installed, it is possible to improve the overall accuracy and to provide a Figure of Merit along with the position (FOM - estimation of the tracking error).

3.2. Tracker Implementation examples

As mentioned above, the concept of tracking a radiator using a dispersed set of 1-axis trackers can be implemented by utilizing a variety of radiation types. For example:

- Radio Frequency (RF)
- Nuclear Gamma emission
- Visible light
- Sound waves
- Etc.

The first two examples seem to be applicable to intravascular tracking systems. And will be depicted in more detail in the following sections.

3.2.1. RF Tracker

The RF tracker is intended to locate a radio frequency radiator or reflector that is placed on a medical tool. The system concept is the same as described above.
The differential sensor for RF is described in the following section.

3.2.1.1. Typical RF antenna gain

Every RF antenna has some level of sensitivity in almost every direction. A typical plot of the antenna gain versus the angle from the antenna's central axis is illustrated in Figure 3.
This figure illustrates how much the antenna increases (or decreases) the signal received from each direction.

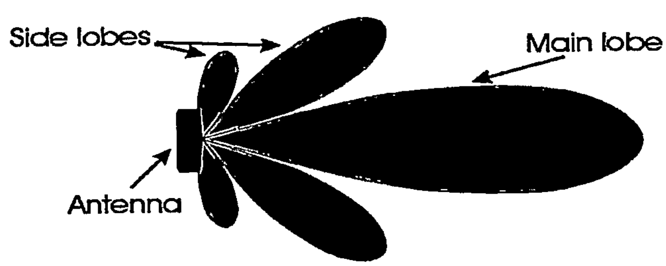

Figure 3 : Typical RF antenna main and side lobes shape

3.2.1.2. Differential RF sensor arrangement

Two antennas can be arranged in a way that their main lobes intersect as in the illustration below:

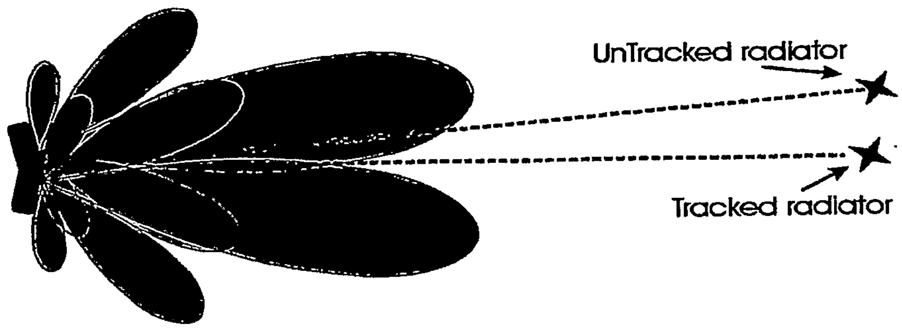

Figure 4 : Differential RF sensor

The antenna cluster can be rotated until the amplitude of the signal is identical in the two antennas. Any movement of the emitter will result in a difference between the readings.
Mechanical measurement of the antenna's orientation in this situation provides the angle from the antenna to the emitter (or reflector) about the axis of rotation of the antenna.

3.2.2. Nuclear tracker

The Nuclear tracker is intended to locate a gamma ray radiator that is placed on a medical tool.
The system concept is the same as described above.
The differential sensor for gamma rays is described in the following section.
Radioactive matter emits particles in random directions. The existing gamma ray sensors can not detect the origin of the radiation i.e. the direction of the ray is unknown. The sensor can become direction-sensitive by installing a collimator on top of it. By doing so, most of the radiation is obscured and thus, the sampling time is increased substantially.
However, the following differential sensor can determine the direction to the radiation source about one axis without obscuring the majority of the incoming radiation (allowing a short sampling time).

3.2.2.1. Differential gamma ray sensor arrangement

Following is an illustration of the nuclear differential sensor.

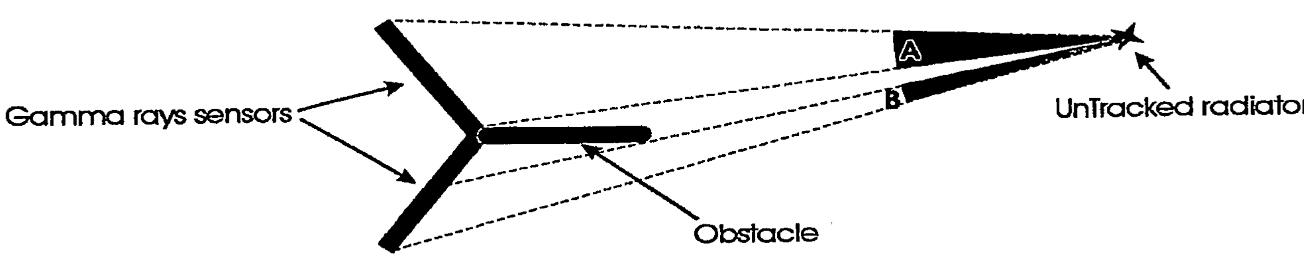

Figure 5 : Nuclear differential sensor

Since the radiation is emitted randomly, the number of particles that are sensed by each sensor is proportional to the spatial angle of the sensor, as viewed from the emitter.

For example, in Figure 5, the red sensor will detect more particles per time unit than the blue sensor, since angle A is larger than B. (assuming accumulating enough data to overcome the quantization noise)
Only when the sensor is pointing directly to the emitter, will the two readings be identical.
As in the RF tracker described above, the sensors cluster can be rotated until the particle hit rate is identical for the two sensors. Mechanical measurement of the sensor's orientation in this situation provides the angle from the sensor to the emitter about the axis of rotation of the sensor.

3.2.2.2. Nuclear tracker implementation guidelines

- The radioactive material may be spread over few millimeters (~10) in order to reduce the maximal local radiation level below the allowed threshold
- Utilizing radioactive materials with different radiation wavelength will allow tracking two point simultaneously, and thus calculating the orientation of the tracker element
- The sensor geometry shall be designed in such manner to maximize the angular sensitivity i.e. maximize the difference between the two sensors cause by angular change

4. System Application example

The proposed tracking solution can be applied to a variety of medical systems.
Three examples of those systems are described further in this document:

- Intravascular navigation system.
- Extra vascular navigation system with flexible catheter.
- Laparoscopy operation guiding system.

4.1. Intravascular navigation system

4.1.1. System Overview

The tracking system shall be integrated into an imaging system (MRI, CT, Etc). A common coordinates system is defined for both systems. The suspected lesion location is measured relative to this coordinate system utilizing the imaging system.
Based on the imaging data, a three dimensional model of the region of interest is generated and presented online to the operator.
During the procedure, the actual catheter tip location is presented on the image in such manner that allows the operator to navigate the catheter directly to the required location.
Accurately reaching a suspected lesion can be utilized for performing biopsy or applying treatment such as:

- Inject medication
- Brachy therapy
- RF radiation
- Freezing
- Stent application
- Etc.

Such a system is most effective in treating lesions with limited or difficult access such as:

- Brain tumors
- Brain aneurisms

- Liver tumors

4.1.2. System block diagram

The following figure illustrates the top level block diagram of the intravascular navigation system:

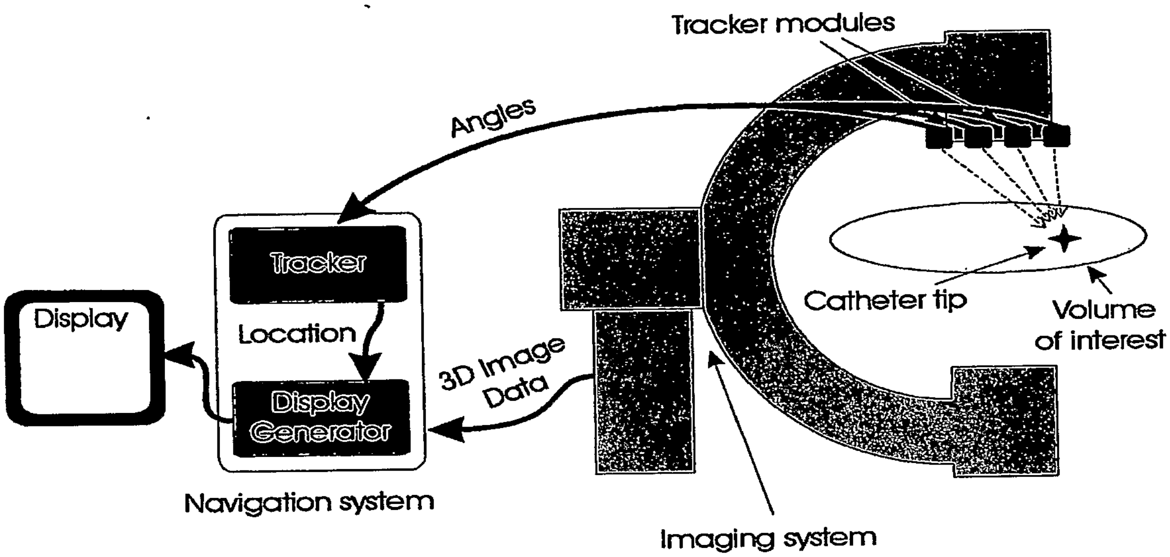

Figure 6 : Intravascular Navigation System block diagram

4.1.3. System highlights

The catheter guidance can be performed inside the imaging system based on updating imaging data or outside the system, based on past images.

Using such system for intravascular treatments will:

- Minimize the damage to healthy tissue
- Minimize the required operator skills
- Expand the treatable population
- Increase the number of successful procedures.